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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,207	02/10/2005	Eric Ezan	265434US0PCT	9997
22850	7590	01/09/2006		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HAQ, SHAFIQU	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 01/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/524,207	EZAN ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/10/05, 5/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. With respect to Claim 1 the structure and chemical nature of the "silylated organic compound" is unclear.
4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: detecting and/or measuring step for the appearance of desilylated organic compound or disappearance of silylated organic compound.
5. Claims 2 and 16 lacks antecedent basis for the term "the formula" in line 1. There is no formula in claim 1.
6. Claim 13 lacks antecedent basis for the term "the pH of the contacting aqueous solution".
7. Claim 14 lacks antecedent basis for the term "the contacting" in line 2.
8. With respect to claim 15, it is unclear what compound(s) or reagent(s) are encompassed by the term "a means for detecting" in the kit claim.
9. Claim 25 lacks antecedent basis for the term "the kit".

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for organic compounds such as steroid, cytokines, estradiol etc., does not reasonably provide enablement for any organic compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides guidance only for use of estradiol and its derivatives, but there is no enablement in the specification for use of all organic compound for "R⁴". For example, lines 21-23 of specification recites that "in order to be able to be silylated, this compound contains at least one hydroxyl function which is accessible for silylation".

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1641

13. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Descalzo et al (The journal of Royal Society of Chemistry, 2002).

Descalzo et al disclose a method for determination of fluoride in a sample (see abstract). Silylated organic compounds are disclosed (see scheme 1 of page 563) and the presence of fluoride in solution liberates organic compound from silica (i.e. desilylated organic compound). The method comprises bringing in contact, in solution, a fluoride sample with silylated organic compound and the liberated organic compound is measured which is indicative of the presence/or concentration of fluoride in a sample (page 562, lines 16-29 of left column and lines 33-45 of right column and scheme 1 of page 563). It is presumed that unsilylated compound (fluorophore) is also measured for comparison with the liberated organic molecule (fluorophore) (see fig. 1).

Therefore, the reference deems to anticipate the cited claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Descalzo et al (The journal of Royal Society of Chemistry, 2002).

Descalzo et al disclose a method for determination of fluoride in a sample using Silylated organic compounds as described above in paragraph 13 but fail to disclose components compiled in a kit. However, the packaging of components in kit form is a well-known obvious expedient for ease and convenience in assay performance and once a method has been established, one skilled in the art would clearly consider compiling in a kit format and change/modify different components of the kit to best suit the assay.

16. Claims 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of 1) Salari (journal of chromatography, 1987, vol 416, pages 219-235) and 2) Tallent et al (Journal of lipid research, 1968, Vol 9, pages 146-148).

The method of use limitation in claim 15 do not affect the composition itself which is composed solely of two components, the silylated compound and the detection and therefore, the use limitation has not ^{been} given any patentable weight.

Salari discloses silylated organic compounds (e.g. trimethylsilyl ester, tert-butylmethylsilyl esters) (see title and page 221) and detection by gas chromatography and mass spectrometry (see figs. 2-7).

Tallent et al. also disclose silylated organic compounds (e.g. silylated BSA) (page 147, left column under results and discussion) and detection by gas chromatography and mass spectrometry (see Fig.1).

Since, packaging of components in kit form is a well-known obvious expedient for ease and convenience in assay performance and once a method has been

Art Unit: 1641

established, one skilled in the art would clearly consider compiling components in a kit format and change/modify different components of the kit to best suit the assay.

Allowable Subject Matter

17. Claims 2-14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1641



SHAFIQUL HAQ
EXAMINER
ART UNIT 1641



MARY E. CEPERLEY
PRIMARY EXAMINER
ART UNIT 1641